

Minutes of the Institute Biosafety Committee Meeting

March 11, 2026

Convened at: 1:00 pm and Adjourned at 1:48 pm

Present: Drs. Gelman (Chair), Ding, Fang, Ionov, Thanavala, Mr. Hartley, Ms. Holtz, Ms Keough and Mr. Flagler.

Absent: Drs. Gerber, McGray, Mr. Atwal

ORSP Staff: Ms Pusateri, Ms Herter, Mr. Caruana and Ms. Bennett

Guests: None

Meeting Place: Virtual meeting/Teams.

Minutes of February 11, 2026 were approved.

Vote: Unanimous.

Adverse Event/Accident/Incident Report

January Employee Health Service report; not submitted

ORSP - No reports.

Old Business

1. Safety Story; this months story highlighted personal protection safety equipment awareness.
2. Laboratory inspections; February inspections pending
 - a. Evans BSL 2 lab: OES to follow up (see checklist).
 - b. Repasky BSL2 lab: OES to follow up (see checklist).
 - c. Webster BSL2+ lab: OES to follow up (see checklist).
3. IRB related Biosafety sponsor questioned the need for Continuing reviews to be performed when they are working with CAR T cells. Sponsor believed that NIH claimed it was not necessary. All documentation has been forwarded to Dr Gelman for further review and will update at next meeting. **Update 3/11:** Determined that continuing reviews will continue to be submitted and approved.

New Business:

1. Lab educational visits:
 - 4 Laboratories were visited March 5th with Dr. Thanavala joining the team.
 - a. Barbi BSL 2+ lab: OES to follow up (see checklist).
 - b. Ding BSL2+ lab: No follow up required.
 - c. Goodrich BSL2 lab: OES to follow up (see checklist).
 - d. Wilde BSL2+ lab: OES to follow up (see checklist).The next inspection date will be Thursday April 16th with Dr. Ionov joining the team.

Protocol review:

16 Biosafety applications were reviewed, 8 were continuing reviews.

3 Protocol referenced CAR T cells modified by Virus

Application for 1720M/Lab Based: Approved.

Reviewed by Dr. Ionov

The Initial application for 26-02-1721 entitled: "Investigating metabolic mechanisms of tumor growth and anti-tumor immunity." PI: Longo, Joseph was approved.

The purpose of this protocol is dissect the metabolic and nutrient processing pathways in tumors and immune cells affects cancer growth.

Biosafety agents include: lentivirus, retrovirus

Application for P-4712325: Approved.

Reviewed by Dr. Gelman

The Initial application for P-4712325, 25-12-1707 entitled: "P 4712325 A Phase 3 Randomized Controlled Trial of Rondecabtagene Autoleucel, An Autologous, Dual-Targeting CD19/CD20 CAR T-Cell Product Candidate, versus Investigator's Choice of CD19 CAR T-Cell Therapy in Patients with Relapsed or Refractory Large B-Cell Lymphoma in the Second-Line Setting (PiNACLE-H2H)." PI: Hernandez-Ilizaliturri, Francisco was approved.

The purpose of this protocol is to investigate the efficacy of a dual CD19/CD20 CAR-T therapy vs. a single target CD19 CAR-T therapy in patients with relapsed or refractory Large B-Cell Lymphoma.

Biosafety agents include: lentivirus

Application for Lab Based: Approved.

Reviewed by Dr. Ding

The amendment for lab based application, 25-07-1682 entitled: "McGray Lab Biosafety." PI: McGray, AJ Robert was approved.

The purpose of this protocol is to add new human cell lines, ovarian cancer patient specimens and a xenograft model to target with BiTE-secreting T cells and CAR-T cells.

Biosafety agents include: retrovirus, adenovirus

1 Protocol referenced CAR T Cells with Gene editing

Application for Lab Based: Approved.

Reviewed by Dr. Fang

The amendment for lab based application, 24-09-1627 entitled: "Combination small molecule inhibitor and T cell immunotherapy approaches in ALL." PI: Niswander, Lisa was approved.

The purpose of this protocol is to add human T cells transduced with chimeric antigen receptors and human leukemia cell lines and xenografts.

Biosafety agents include: lentivirus, gilteritinib, trametinib

Exempt from full committee review: none

Amendments:

Application for Lab: Approved.

Reviewed by Dr. Gelman

The amendment to Lab based 25-01-1650 entitled: "COMBINING TARGETED THERAPIES AND IMMUNOTHERAPY IN CANCER TREATMENT (EXPERIMENTAL)" PI: Ding, Liya was approved on 2/13/2026.

Biosafety agents used include: New cell lines.

Application for Lab: Approved.

Reviewed by Dr. Gelman

The amendment to Lab based 24-02-1563 entitled: "Characterizing the host immune response to flagellin-based agonists" PI: Brackett, Craig was approved 2/19/2026.

Biosafety agents used include: cell lines and compounds.

Application for Lab/1183M: Approved.

Reviewed by Dr. Gelman

The amendment to Lab based/1183M 25-08-1689 entitled: "Evaluation of the Safety and Efficacy of Novel Combination Therapies and Preventions of Oral and Head and Neck Cancers" PI: Seshadri, Mukund was approved 2/20/2026.

Biosafety agents used include: cell lines and compounds.

Application for Lab: Approved.

Reviewed by Dr. Gelman

The amendment to Lab based 24-03-1572 entitled: "Enhancement of PDT Using Biological Response Modifiers" PI: Shafirstein, Gal was approved 2/24/2026.

Biosafety agents used include: human cell lines and specimens.

See attached for complete list.

Respectfully Submitted,



Irwin Gelman, PhD
Institute Biosafety Committee Chair
Director of Research Integration; Professor of
Oncology